

REMARKS

Claims 1 – 9 are currently pending and under examination.

Claims 1-3 and 5-8 have been canceled.

Claim 4 has been amended *supra* to incorporate the enumerated compounds identified in now canceled claims 5 and 6.

Claim 4 has been further amended to correct a much regretted typographical error correcting the naming of dihydro-adhumulone to dihydro-isoadhumulone. The Applicants aver that this amendment does not add new subject matter as support may be found in the chemical structure as depicted in Figure 3C. Claim 4 has been further amended to reflect that the R1AA and 1AA are in synergistic amounts in the therapeutically effective ratios. Support for such amendment may be found at, for example, Example 4, Table 6, and Figure 4 of the Specification.

New claims 9-13 have been added. Support for these claims can be found in the specification as filed at, for example, page 16, paragraph 59, lines 7-9; page 17, paragraphs 62 and 63. The Applicants respectfully request entry of the claims as amended.

I. Claim Objections

Claims 2-3, and 5-6 were objected to under 37 CFR 1.75(c) as being of improper dependent form. Claims 2-3 have been canceled and removed from examination by way of amendment. Claims 5-6 have been canceled and the enumerated compounds incorporated into currently pending claim 4 by way of amendment. As such, Applicants respectfully request the withdrawal of the objection to 5-6 under 37 CFR 1.75(c) as being of improper dependent form.

II. CLAIM REJECTIONS UNDER 35 USC § 102(e)

Claims 1-3 and 8 stand rejected under 35 USC § 102(e) as being anticipated by Shahlal et al. (US 6,583,322).

Claims 1-3 and 8 have been canceled by way of amendment. As such Applicants respectfully request that this rejection be withdrawn.

III. CLAIM REJECTIONS UNDER 35 USC § 103(a)

Claims 1-9 stand rejected under 35 USC § 103(a) as being unpatentable over Kuhrts (US 2004/0137096, herein after “Kuhrts”).

The Office contends that “Kuhrts teaches a pharmaceutical composition comprising hops extract consisting of iso-alpha acids (IAA), and reduced iso-alpha acids (RIAA) such as . . . dihydroiso-humulone, and combinations thereof. It is also disclosed that iso-alpha acids which are combinations of reduced isoalpha acid (RIAA) and isoalpha acid (IAA) will be present in an amount of 0.05% to 10% by weight in the hops extract.” Office Action, page 5.

The Office acknowledges that “Kuhrts does not expressly teach the ratio of reduced isoalpha acid:isoalpha acid of about 3:1 to about 1:10, in the composition. Kuhrts does not expressly teach that the composition contains at least 0.1% of RIAA and IAA individually.” Office Action, page 5. Nevertheless, the Office concludes that “[i]t would have been obvious to a person of ordinary skill in the art at the time of the invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid employed in the composition of Kuhrts, to obtain a desired effect such as reducing inflammation.” Office Action, page 6. Applicants respectfully traverse.

Applicants submit that they have discovered that compositions of reduced isoalpha acids (i.e., dihydro isoalpha acids) and isoalpha acids, when combined in certain ratios and within that ratio in certain amounts, have unexpected synergistic anti-inflammatory effects. See the entire application as filed and, for example, the title and abstract and Example 4. Accordingly, the claims reflect the finding of synergism. Kuhrts does not teach or suggest the element of “synergy” as claimed or taught by the present invention.

Claim 4 has been amended to reflect that within the claimed ratios that the RIAA and IAA are in synergistic amounts.

The specification discloses that “synergy was noted for all RIAA:IAA combinations, albeit at different segments of the dose-response curves.” See Example 4 of the application as filed on page 31, paragraph [0104] to page 32. This unexpected finding showed that while RIAA and IAA could act synergistically over a wide range of ratios and concentrations as shown in

Figures 4A-H of the specification, they also act additively or even antagonistically at certain other concentrations. See Figures 4A-H for tabulated CI (Combination Index) values and the specification on pages 30-31, paragraph [0100], which defines CI values of <1 , $=1$, and >1 to indicate synergism, additivity and antagonism, respectively. The Examiner's attention is directed to Figure 4E which specifically demonstrates synergy wherein the RIAA and IAA each comprise at least 0.1% of the composition (see shaded area).

Thus, in view of the present specification, the synergistic property of a given combination of RIAA and IAA was shown to be unpredictable prior to Applicants' discovery. In KSR, the Supreme Court reaffirmed that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 82 USPQ2d at 1395 1395-97 (2007); MPEP § 2141 guidelines for determining obviousness. However, as described above, by discovering synergism between the compounds claimed, Applicants have shown more than predictable results.

Furthermore, as described in Example 4 of the application and shown in Figures 4A-H, Applicants not only have discovered specific ratios in which RIAA and IAAs act synergistically (which is an effect greater than the expected sum of the additive effect of each compound taken separately), but they have also discovered ratios at which the mixture of RIAA and IAA act antagonistically. Thus, the applicants have discovered heretofore unknown properties of the claimed mixtures that give rise to unexpected results.

Therefore, in view of the information disclosed in the present specification and the claims, Applicants submit that at the time of filing of the application, a skilled artisan who was familiar with the teachings of Kuhrt could not have distinguished between the additive or antagonistic and beneficially synergistic interactions of the compounds presently claimed. Accordingly, the skilled artisan would not have had a reasonable expectation of success in combining the compounds of Kuhrt or optimizing parameters to arrive at the presently claimed ratios. As such, Applicants respectfully submit that the invention as claimed is unobvious over Kuhrt and respectfully request withdrawal of the 35 USC § 103(a) rejection.

IV. CONCLUSION

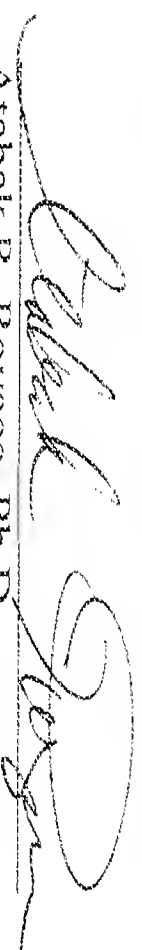
On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 4 and 9 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, The Examiner is requested to call Applicants' agent at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including June 10, 2010 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(3), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.117 applicable in this instant, as well as in future communications to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate time pursuant to 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectively submitted,

MCDERMOTT WILL & EMERY LLP

A handwritten signature in dark ink, appearing to read 'Atabak R. Royace', is written over a horizontal line.

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